Complete Summary

GUIDELINE TITLE

Guidelines on neurogenic lower urinary tract dysfunction.

BIBLIOGRAPHIC SOURCE(S)

Stohrer M, Castro-Diaz D, Chartier-Kastler E, Del Popolo G, Kramer G, Pannek J, Radziszewski P, Wyndaele JJ. Guidelines on neurogenic lower urinary tract dysfunction. Arnhem, The Netherlands: European Association of Urology (EAU); 2008 Mar. 60 p. [470 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

 December 04, 2007, Desmopressin Acetate (DDAVP, DDVP, Minirin, & Stimate): New information has been added to the existing boxed warning in Desmopressin's prescribing information about potential increased risk for severe hyponatremia and seizures.

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** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Neurogenic lower urinary tract dysfunction

GUIDELINE CATEGORY

Diagnosis Management Risk Assessment Treatment

CLINICAL SPECIALTY

Neurology Surgery Urology

INTENDED USERS

Managed Care Organizations Physicians

GUIDELINE OBJECTIVE(S)

To provide useful information for clinical practitioners on the incidence, definitions, diagnosis, therapy, and follow-up observation of the condition of neurogenic lower urinary tract dysfunction (NLUTD)

TARGET POPULATION

Patients with lower urinary tract dysfunction resulting from neurologic problems

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Assessment

- 1. Assessment of risk factors and epidemiology
- 2. Classification of neurogenic lower urinary tract dysfunction (NLUTD)
- 3. General and specific (urinary, bowel, sexual, neurological) medical history
- 4. General and neuro-urological physical examination
- 5. Urodynamic assessment (bladder diary, free uroflometry, filling cystometry, detrusor leak point pressure, pressure flow study, electromyography, urethral pressure measurement, video and ambulatory urodynamics, provocative tests during urodynamic studies)
- 6. Assessment of quality of life

Treatment/Management

- 1. Non-invasive conservative treatment
 - Assisted bladder emptying
 - Lower urinary tract rehabilitation
 - Drug treatment (anticholinergics, oxybutynin, propiverine, darifenacin, solifenacin, phosphodiesterase inhibitors, desmopressin)
 - Electrical neuromodulation, pelvic floor muscle exercise (PFME)
 - External appliances
- 2. Minimal invasive treatment
 - Catheterization
 - Intravesical drug treatment (anticholinergics, vanilloids, capsaicin, resiniferatoxin)
 - Intravesical electrostimulation
 - Botulinum toxin injections
 - Bladder neck and urethral procedures
- 3. Surgery
 - Urethral and bladder neck procedures
 - Detrusor myectomy
 - Denervation, deafferentation, neurostimulation, neuromodulation
 - Bladder covering by striated muscle
 - Bladder augmentation or substitution
 - Urinary diversion
- 4. Treatment of vesico-ureteral reflux
- 5. Follow-up schedule

MAJOR OUTCOMES CONSIDERED

- Quality of life/patient satisfaction
- Frequency of urinary tract infections and other morbidity from procedures
- Rate of improvement in urinary continence and restoration of lower urinary tract function

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Up until 2007, the main strategy was to rely on the guidelines group members' knowledge and expertise on the current literature assuming that all, or almost all, relevant information would be captured.

In updates produced from 2008 onwards, a structured literature search will be performed for all guidelines but this search will be limited to randomized controlled trials and meta-analyses, covering at least the past three years, or up until the date of the latest text update if this exceeds the three-year period. Other excellent sources to include are other high-level evidence, Cochrane review and available high-quality guidelines produced by other expert groups or organizations. If there are no high-level data available, the only option is to

include lower-level data. The choice of literature will be guided by the expertise and knowledge of the Guidelines Working Group.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- 1a Evidence obtained from meta-analysis of randomized trials
- **1b** Evidence obtained from at least one randomized trial
- **2a** Evidence obtained from one well-designed controlled study without randomization
- **2b** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **3** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **4** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

• The first step in the European Association of Urology (EAU) guidelines procedure was to define the main topic.

- The second step was to establish a working group. The working groups comprise about 4-8 members, from several countries. Most of the working group members are academic urologists with a special interest in the topic. Specialists from other medical fields (radiotherapy, oncology, gynaecology, anaesthesiology, etc.) are included as full members of the working groups as needed. In general, general practitioners or patient representatives are not part of the working groups. Each member is appointed for a four-year period, renewable once. A chairman leads each group.
- The third step is to collect and evaluate the underlying evidence from the published literature.
- The fourth step is to structure and present the information. All main recommendations are summarized in boxes and the strength of the recommendation is clearly marked in three grades (A-C), depending on the evidence source upon which the recommendation is based. Every possible effort is made to make the linkage between the level of evidence and grade of recommendation as transparent as possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical trials
- C. Made despite the absence of directly applicable clinical studies of good quality

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was used to analyse and assess a range of specific attributes contributing to the validity of a specific clinical guideline.

The AGREE instrument, to be used by two to four appraisers, was developed by the AGREE collaboration (www.agreecollaboration.org) using referenced sources for the evaluation of specific guidelines. (See the "Availability of Companion Documents" field for further methodology information).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (1a-4) and grades of recommendation (A-B) are provided at the end of the "Major Recommendations" field.

Classification of Neurogenic Lower Urinary Tract Dysfunction (NLUTD)

The Madersbacher classification system (Wyndaele et al., 2005; Madersbacher, 1990) (see Figure 2.1 in the original guideline document) is recommended for clinical practice (**Grade of recommendation: B**).

Diagnosis

History

- 1. An extensive general history is mandatory, concentrating on past and present symptoms and conditions for urinary, bowel, sexual, and neurological functions, and on general conditions that might impair any of these.
- 2. Special attention should be paid to the possible existence of alarm signs, such as pain, infection, haematuria, fever, etc., that warrant further specific diagnosis.
- 3. A specific history should be taken for each of the four mentioned functions.

Physical Examination

- 1. Individual patient handicaps should be acknowledged in planning further investigations.
- 2. The neurological status should be described as completely as possible. Sensations and reflexes in the urogenital area must all be tested.
- 3. The anal sphincter and pelvic floor functions must be tested extensively.
- 4. Urinalysis, blood chemistry, voiding diary, residual and free flowmetry, incontinence quantification and urinary tract imaging should be performed.

Urodynamics and Uro-neurophysiology

- 1. Urodynamic investigation is necessary to document the (dys-)function of the lower urinary tract (LUT) (**Grade of recommendation: A**).
- The recording of a bladder diary is advisable (Grade of recommendation: B).
- 3. Non-invasive testing is mandatory before invasive urodynamics is planned (**Grade of recommendation: A**).
- 4. Video-urodynamics is the gold standard for invasive urodynamics in patients with NLUTD. If this is available, then a filling cystometry continuing into a pressure flow study should be performed (**Grade of recommendation: A**).
- 5. A physiological filling rate and body-warm saline must be used (**Grade of recommendation: A**).
- 6. Specific uro-neurophysiological tests are elective procedures (**Grade of recommendation: C**).

Treatment

Non-invasive Conservative Treatment

Conclusions

- Long-term efficacy and safety of anticholinergic therapy for neurogenic detrusor overactivity (NDO) is well documented (**Level of evidence: 1a, Grade of recommendation: A**).
- A combination of therapies is often considered to maximize outcomes for NDO (Level of evidence: 1a, Grade of recommendation: A).
- There is no drug with evidence of efficacy for underactive detrusor (**Level of evidence: 2a, Grade of recommendation: B**).
- Alpha-blockers have been partly successful for decreasing bladder outlet resistance and autonomic dysreflexia prophylaxis in spinal cord injury (SCI) patients (**Level of evidence: 2a, Grade of recommendation: B**).
- There is a lack of prospective randomized controlled studies in the medical management of NLUTD.

Guidelines for Non-Invasive Conservative Treatment

- 1. The first aim of any therapy is the protection of the upper urinary tract.
- 2. The mainstay of treatment for overactive detrusor is anticholinergic drug therapy (**Level of evidence: 1, Grade of recommendation: A**).
- 3. Lower urinary tract rehabilitation may be effective in selected cases.
- 4. A condom catheter or pads may reduce urinary incontinence to a socially acceptable situation.
- 5. Any method of assisted bladder emptying should be used with the greatest caution (**Grade of recommendation: A**).

Catheterization

- 1. Intermittent catheterization (IC) is the standard treatment for patients who are unable to empty their bladder (**Level of evidence: 2, Grade of recommendation: A**).
- 2. Patients should be well instructed in the technique and risks of IC.
- 3. Aseptic IC is the method of choice (Level of evidence: 2, Grade of recommendation: B).
- 4. The catheter size should be 12-14 Fr (**Grade of recommendation: B**).
- 5. The frequency of IC is 4 to 6 times per day (**Grade of recommendation: B**).
- 6. The bladder volume should remain below 400 mL (**Grade of recommendation: B**).
- 7. Indwelling transurethral and suprapubic catheterization should be used only exceptionally, under close control, and the catheter should be changed frequently. Silicone catheters are preferred and should be changed every 2 to 4 weeks, while (coated) latex catheters need to be changed every 1 to 2 weeks. (**Grade of recommendation: A**).

Minimal Invasive Treatment

- 1. See the guidelines for catheterization above.
- 2. Botulinum toxin injection in the detrusor is the most effective minimally invasive treatment to reduce neurogenic detrusor overactivity (**Level of evidence: 1, Grade of recommendation: A**).
- 3. Sphincterotomy is the standard treatment for detrusor sphincter dyssynergia (DSD) (**Level of evidence: 2, Grade of recommendation: A**).

4. Bladder neck incision is effective in a fibrotic bladder neck (**Level of evidence: 3, Grade of recommendation: B**).

Surgical Treatment

- 1. Detrusor
 - Overactive
 - Detrusor myectomy is an acceptable option for the treatment of overactive bladder when more conservative approaches have failed. It is limited invasive and has minimal morbidity (Level of evidence: 2, Grade of recommendation: B).
 - Sacral rhizotomy with sacral anterior root stimulation (SARS) in complete lesions and sacral neuromodulation in incomplete lesions are effective treatments in selected patients (Level of evidence: 2, Grade of recommendation: B).
 - Bladder augmentation is an acceptable option for decreasing detrusor pressure whenever less invasive procedures have failed. For the treatment of a severely thick or fibrotic bladder wall, a bladder substitution might be considered (Level of evidence: 2, Grade of recommendation: B).
 - Underactive
 - SARS with rhizotomy and sacral neuromodulation are effective in selected patients (Level of evidence: 2, Grade of recommendation: B).
 - Restoration of a functional bladder by covering with striated muscle is still experimental (**Level of evidence: 4**).

2. Urethra

- Overactive (DSD): refer to guidelines for minimal invasive treatment above
- Underactive
 - The placement of a urethral sling is an established procedure (Level of evidence: 2, Grade of recommendation: B).
 - The artificial urinary sphincter is very effective (Level of evidence: 2, Grade of recommendation: B).
 - Transposition of the gracilis muscle is still experimental (Level of evidence: 4).

Quality of Life (QoL)

- 1. Assess QoL to evaluate lower urinary tract symptoms (LUTS) in neurogenic patients and during any type of treatment for neurogenic bowel dysfunction (Level of evidence 2a, Grade of recommendation: B).
- 2. Available tools are: Qualiveen, a specific tool for spinal cord lesion and multiple sclerosis patients, Visual Analogue Scale (VAS) for bother. However, generic (SF-36) or specific tools for incontinence (I-QOL) questionnaires could be used too. (**Level of evidence: 2a, Grade of recommendation: B**).
- 3. There is a lack of disease-specific outcome measures assessing health-related QoL in patients with NLUTD.

Follow-Up

- 1. Possible urinary tract infection (UTI) checked by the patient (dip stick).
- 2. Urinalysis every second month.
- 3. Upper urinary tract, bladder morphology, and residual urine every 6 months (ultrasound).
- 4. Physical examination, blood chemistry, and urine laboratory every year.
- 5. Detailed specialist investigation every 1 to 2 years and on demand when risk factors emerge. The investigation is specified according to the patient's actual risk profile, but should in any case include a video-urodynamic investigation and should be performed in a leading neuro-urological centre.
- 6. All of the above should be more frequent if the neurological pathology or the NLUTD status demands this.

Definitions:

Levels of Evidence

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- **2a** Evidence obtained from one well-designed controlled study without randomization
- **2b** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **3** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **4** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

Grades of Recommendation

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- B. Based on well-conducted clinical studies, but without randomized clinical trials
- C. Made despite the absence of directly applicable clinical studies of good quality

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of neurogenic lower urinary tract dysfunction

POTENTIAL HARMS

- Drug therapy carries the risk of side effects.
- Indwelling transurethral catheterization and, to a lesser extent, suprapubic cystostomy are significant and early risk factors for urinary tract infection (UTI) and other complications.
- Secondary narrowing of the bladder neck may occur with sphincterectomy, for which combined bladder neck incision might be considered.
- Increasing the bladder outlet resistance has the inherent risk of causing high intravesical pressure during the filling, which may become even higher during the voiding phase.
- The continent stoma is created following various techniques. All of them, however, do show frequent complications, including leakage or stenosis.

CONTRAINDICATIONS

CONTRAINDICATIONS

Because of the risk of developing high intravesical pressure, the penile clamp is absolutely contraindicated.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The purpose of this text is not to be proscriptive in the way a clinician should treat a patient but rather to provide access to the best contemporaneous consensus view on the most appropriate management currently available. European Association of Urology (EAU) guidelines are not meant to be legal documents but are produced with the ultimate aim to help urologists with their day-to-day practice.
- The EAU believe that producing validated best practice in the field of urology is a very powerful and efficient tool in improving patient care. It is, however, the expertise of the clinician which should determine the needs of their patients. Individual patients may require individualized approaches which take into account all circumstances and treatment decisions often have to be made on a case-by-case basis.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The European Association of Urology (EAU) Guidelines long version (containing all 19 guidelines) is reprinted annually in one book. Each text is dated. This means that if the latest edition of the book is read, one will know that this is the most updated version available. The same text is also made available on a CD (with hyperlinks to PubMed for most references) and posted on the EAU websites Uroweb and Urosource (www.uroweb.org/professional-resources/guidelines/ & http://www.urosource.com/diseases/).

Condensed pocket versions, containing mainly flow-charts and summaries, are also printed annually. All these publications are distributed free of charge to all (more than 10,000) members of the Association. Abridged versions of the guidelines are published in European Urology as original papers. Furthermore, many important websites list links to the relevant EAU guidelines sections on the association websites and all, or individual, guidelines have been translated to some 15 languages.

IMPLEMENTATION TOOLS

Pocket Guide/Reference Cards Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Stohrer M, Castro-Diaz D, Chartier-Kastler E, Del Popolo G, Kramer G, Pannek J, Radziszewski P, Wyndaele JJ. Guidelines on neurogenic lower urinary tract dysfunction. Arnhem, The Netherlands: European Association of Urology (EAU); 2008 Mar. 60 p. [470 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Mar

GUIDELINE DEVELOPER(S)

European Association of Urology - Medical Specialty Society

SOURCE(S) OF FUNDING

European Association of Urology

GUIDELINE COMMITTEE

Neurogenic Lower Urinary Tract Dysfunction Guidelines Writing Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: M.Stöhrer; D. Castro-Diaz; E. Chartier-Kastler; G. Del Popolo; G. Kramer; J. Pannek; P. Radziszewski; J-J. Wyndaele

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Neurogenic Lower Urinary Tract Dysfunction guidelines writing panel have provided disclosure statements of all relationships which they have and which may be perceived as a potential source of conflict of interest. The information is kept on file in the European Association of Urology (EAU) database. This guidelines document was developed with the financial support of the EAU. No external sources of funding and support have been involved. The EAU is a non-profit organisation and funding is limited to administrative assistance, travel, and meeting expenses. No honoraria or other reimbursements have been provided.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the European Association of Urology Web site.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- EAU guidelines office template. Arnhem, The Netherlands: European Association of Urology (EAU); 2007. 4 p.
- The European Association of Urology (EAU) guidelines methodology: a critical evaluation. Arnhem, The Netherlands: European Association of Urology (EAU); 18 p.
- Guidelines on neurogenic lower urinary tract dysfunction. 2008, Ultra short pocket guidelines. Arnhem, The Netherlands: European Association of Urology (EAU); 2008 Mar. 13 p.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

PATIENT RESOURCES

None available

NGC STATUS

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